SPECIFICATION

(Case No. 98,420)

TO ALL WHOM IT MAY CONCERN:

Be it known that we, MARK T. RISE, a citizen of the United States and resident of Monticello, Minnesota, and MICHAEL D. BAUDINO, a citizen of the United States and resident of Coon Rapids, Minnesota, have invented certain new and useful improvements in

TECHNIQUES FOR SELECTIVE ACTIVATION OF NEURONS IN THE BRAIN, SPINAL CORD PARENCHYMA OR PERIPHERAL NERVE

of which the following is a specification.

Assignee: Medtronic, Inc.
7000 Central Avenue, N.E.
Minneapolis, Minnesota 55432

BACKGROUND OF THE INVENTION

This patent application is a continuation of U.S. Patent Application Serial No. 09/302,519, filed April 30, 1999, now U.S. Patent No. 6,353,762 for which priority is claimed. This parent application is incorporated herein by reference in its entirety.

Field of the Invention

The present Invention relates to techniques for providing treatment therapy to neural tissue, and more particularly relates to techniques for selectively delivering treatment therapy to neural tissue located within a volume of the brain, spinal cord, or peripheral nerve.

Description of Related Art

Electrical stimulation techniques have become increasingly popular for treatment of pain and various neurological disorders. Typically, an electrical lead having one or more electrodes is implanted near a specific site in the brain or spinal cord of a patient. The lead is coupled to a signal generator which delivers electrical energy delivered through the electrodes creates an electrical field causing excitation of the nearby neurons directly or indirectly treat the pain or neurological disorder.

Presently, only highly skilled and experiences practitioners are able to position a stimulation lead in such a way that the desired volume of brain tissue is influences and desired results are obtained over time with minimal side effects. It requires much time and effort to focus the stimulation on the population of nerve cells subserving the appropriate function in the desired body region during surgery. These leads cannt be moved by the physician without requiring a second surgery.

A major practical problem with these systems is that the response of the nervous system may change in time. For example, when treating pain even if paresthesia covers the area in pain perfectly during surgery, the required paresthesia pattern often changes later due to lead migration,

histological changes (such as the growth of connective tissue around the stimulation electrode), neural plasticity or disease progression. As a result, the electrical energy is directed to stimulate undesired portions of the brain or spinal cord. Redirecting paresthesia without requiring a second surgery is therefore highly desirable. With present single channel, linear electrode array approaches, however, it is difficult to redirect stimulation effects afterwards, even though limited readjustments can be made by selecting a different contact combination, pulse rate, pulse width or voltage. These problems are found not only with spinal cord stimulation (SCS), but also with peripheral nerve stimulation (PNS), depth brain stimulation (DBS), cortical stimulation and also muscle or cardiac stimulation.

In the case of DBS where an electrical lead is implanted within the brain, it is particularly critical that the lead be properly positioned. If the lead is not properly positioned and needs to be moved, it must be removed and re-inserted thereby increasing the risk of bleeding and damage to the neuropile. It is therefore desirable to place the lead within the brain in one attempt and avoid subsequent movement or repositioning of the lead.

Recent advances in this technology have allowed the treating physician or the patient to steer the electrical energy delivered by the electrode once it has been implanted within the patient. For example, U.S. Patent No. 5,713,922 entitled "Techniques for Adjusting the Locus of Excitation of Neural Tissue in the Spinal Cord or Brain," issued on February 3, 1998 to and assigned to Medtronic, Inc. discloses one such example of a system for steering electrical energy. Other techniques are disclosed in Application Serial Nos. 08/814,432 (filed March 10, 1997) and 09/024,162 (filed February 17, 1998). Changing the electric field distribution changes the distribution of neurons

recruited during a stimulus output thus provides the treating physician or the patient the opportunity to alter the physiological response to the stimulation. The steerability of the electric field allows the user to selectively activate different groups of nerve cells without physically moving the electrode.

These steering techniques, however, are limited to primarily two-dimensional steering since the electrodes are positioned in a linear or planar configuration. In the case of deep brain stimulation (DBS), the stimulation treatment requires stimulation of a volume of neural tissue. Since the exact location of the desired tissue is unknown, it is desirable to steer the electrical field in more than just two-dimensional space.

Another problem with DBS is that the insertion of electrical leads within the brain presents risks of bleeding or damage to the brain tissue. Where multiple leads are inserted within the brain, this risk also multiplies. Often during placement of a lead within the brain, the lead is not placed in the desired location. The lead must be removed and re-inserted into the brain. Each re-insertion of the lead poses additional risk of injury.

Accordingly, there remains a need in the art to provide a two- or three-dimensional steerable electrical stimulation device that may be implanted within the brain or spinal cord parenchyma that requires minimal adjustment of the lead position.

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Ten S. Wacker Drive, Ste. 3000
Chicago, Illinois 60606
Telephone: 312/715-1000
Fax: 312/715-1234

SUMMARY OF THE INVENTION

As explained in more detail below, the present invention overcomes the above-noted and other shortcomings of prior techniques for electrical stimulation of the brain, spinal cord parenchyma and peripheral nerve. The present invention provides a technique for insertion of electrode leads that require minimal adjustment once the lead has been inserted. Additionally, the present invention enables the user to selectively stimulate neurons or neural tissue within a specific volume of tissue. In a preferred embodiment, the present invention includes a cannula, a plurality of leads, and at least one therapy delivery element or electrode at the distal ends of each of the leads. The cannula has a lumen and at least two openings at its distal end. The leads may be inserted into the cannula's lumen and projected outward at the distal end from each of the openings along a predetermined trajectory. A therapy delivery device, such as a signal generator, is coupled to one or more therapy delivery elements, such as electrodes. The signal generator is capable of selectively providing electrical energy via the electrode to create an electrical field. The system may selectively adjust the electrical field created by the electrical energy. Optionally, a sensor may be included for generating a signal related to the extent of a physical condition for treating a neurological disorder or pain. The sensor signal may then be used to adjust at least one parameter of the electrical energy provided to the electrode.

In another embodiment, the present invention is implemented within a drug delivery system. In such a case, the therapy delivery device may be a pump and the therapy delivery element is a catheter. Alternatively, both electrical stimulation and drug delivery may be implemented.

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Ten S. Wacker Drive, Ste. 3000
Chicago, Illinois 60606
Telephone: 312/715-1000
Fax: 312/715-1234

By using the foregoing techniques, electrical stimulation and/or drug delivery may be adjusted and/or steered to a precise target within a volume of neural tissue to provide the desired treatment therapy. Further, the present invention provides a method of lead placement that allows the surgeon to explore a larger volume of brain tissue using only a single pass of the lead introducer into the brain which will reduce the inherent risk of surgery. Examples of the more important features of this invention have been broadly outlined above so that the detailed description that follows may be better understood and so that contributions which this invention provides to the art may be better appreciated. There are, of course, additional features of the invention which will be described herein and which will be included within the subject matter of the claims appended hereto.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other advantages and features of the invention will become apparent upon reading the following detailed description and referring to the accompanying drawings in which like numbers refer to like parts throughout and in which:

Figure 1 is a schematic view of a patient having an implant of a neurological stimulation system employing a preferred form of the present invention to stimulate the subthalamic nucleus of the patient;

Figure 2 is a cross sectional view of brain B showing implantation of a cannula within the brain;

Figure 3 is a sagittal view of a subthalamic nucleus showing implantation of electrical leads having electrodes at the distal ends;

Figures 4-7 are exemplary illustrations of various electrical lead configurations capable of selectively stimulating a volume of neural tissue in accordance with the present invention;

Figure 8 is an illustration of a cannula in accordance with a preferred embodiment of the present invention;

Figures 9 and 9A are cross sectional views of a cannula in accordance with another embodiment of the invention;

Figure 10 is an illustration of a guiding mechanism to be inserted within a cannula for directing the trajectory of the electrical leads of the present invention;

Figure 11 is an illustration of another embodiment of the present invention wherein one or more drugs are delivered;

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Ten S. Wacker Drive, Ste. 3000
Chicago, Illinois 60606
Telephone: 312/715-1000
Fax: 312/715-1234

Figures 12A-B illustrate another embodiment of the present invention wherein the outer leads are pre-formed so that the distal ends will curl out from the inner lead when unconstrained by an introducing cannula;

Figure 13 is a schematic block diagram of a microprocessor and related circuitry used in the preferred embodiment of the invention;

Figures 14-18 are flow charts illustrating a preferred form of a microprocessor program for generating stimulation pulses to be administered to the brain;

Figure 19 is a schematic block diagram of a sensor and analog to digital converter circuit used in the preferred embodiment of the invention;

Figure 20 is a flow chart illustrating a preferred form of a microprocessor program for utilizing the sensor to control the treatment therapy of the brain;

Figure 21 is a cross-sectional view of the present invention implanted subdurally within the cerebral spinal fluid;

Figure 22 is a cross-sectional view of the present invention implanted subdurally within spinal cord parenchyma; and

Figure 23 is a cross-sectional view of the present invention implanted within a peripheral nerve.

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Chicago, Illinois 60606
Telephone: 312/715-1000
Fax: 312/715-1234

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figure 1 is a schematic view of a patient 10 having an implant of a neurological stimulation system employing a preferred form of the present invention to stimulate the subthalamic nucleus of the patient. The preferred system employs an implantable therapy delivery device or a pulse generator 14 to produce a number of independent stimulation pulses which are sent to a region of the brain parenchyma such as the subthalamic nucleus by insulated leads coupled to therapy delivery devices or electrodes 16A-18A (Figure 3). Each lead is inserted within cannula 22A. Alternatively, two or more electrodes 16A-18A may be attached to separate conductors included within a single lead. Figure 2 is a cross section of brain B showing implantation of cannula 22A within the brain. The specific locations within the brain are discussed in further detail herein.

Device 14 is implanted in a human body 120 in the location shown in Figure 1. Body 120 includes arms 122 and 123. Alternatively, device 14 may be implanted in the abdomen or any other part of the body.

Implantable pulse generator 14 is preferably a modified implantable pulse generator available from Medtronic, Inc. under the trademark ITREL II with provisions for multiple pulses occurring either simultaneously or with one pulse shifted in time with respect to the other, and having independently varying amplitudes and pulse widths. This preferred system employs a programmer 20 which is coupled via a conductor 31 to a telemetry antenna 24. The system permits attending medical personnel to select the various pulse output options after implant using telemetry communications. While the preferred system employs fully implanted elements, systems employing partially implanted generators and radio-frequency coupling may also be used in the practice of the

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Ten S. Wacker Drive, Ste. 3000
Chicago, Illinois 60606
Telephone: 312/715-1000
Fax: 312/715-1234

present invention (e.g., similar to products sold by Medtronic, Inc. under the trademarks X-trel and Mattrix).

Figure 3 is a sagittal view of the subthalamic nucleus 10 of brain B at approximately 11mm lateral to the midline. The distal ends of insulated leads 16-18 within cannula 22A terminate in electrodes 16A-18A. The electrodes may be conventional DBS™ electrodes, such as model 3387 sold by Medtronic, Inc. Alternatively, electrodes 16A-18A may be constructed like electrical contacts 56, 58 and 60 shown in PCT International Publication No. WO 95/19804, entitled "Multichannel Apparatus for Epidural Spinal Cord Stimulation" (Holsheimer et al., filed 24 January 1994, published 27 July 1995) which is incorporated by reference in its entirety. Electrodes 16A-18A are positioned in a two- or three-dimensional predetermined geometric configuration as described in further detail herein such that they are distributed throughout various portions of a volume of brain parenchyma such as the subthalamic nucleus. An anode/cathode relationship is established between electrodes 16A-18A in the manner described in PCT Publication No. WO 95/19804. For example, electrodes 16A and 18A may be established as anodes (+) and electrode 17A may be established as a cathode (-). The physician or patient may configure the system to utilize any combination of electrodes 16A-18A to selectively establish a locus of action potentials.

Pulses may then be applied to specific electrodes as taught in the PCT Publication No. WO 95/19804 to direct a locus of action potentials in the brain. Pulses in electrodes 16A-18A create a locus of excitation of nerve cells. As preferred, the electrical pulses are independently adjustable within each electrode such that the locus of excitation may be adjusted to deliver the desired therapy.

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Ten S. Wacker Drive, Ste. 3000
Chicago, Illinois 60606
Telephone: 312/715-1000
Fax: 312/715-1234

For example, the pulses may overlap in time and may be independently variable in amplitude to best control the areas of activation, or they may also have independently variable pulse widths.

In accordance with the present invention, a volume of neural tissue may be stimulated by placement of electrical leads in a non-linear configuration. Figures 4-7 illustrate various electrical lead configurations capable of selectively stimulating a volume of neural tissue. Lead 400 of Figure 4 includes six electrodes at its distal end defining the sides of a cube 405 as shown in Figure 4A. Cube 405 roughly represents the volume of brain parenchyma that electrodes may potentially stimulate. The subset of tissue actually stimulated is determined by the selection of the particular electrodes to pulse and the pulsing parameters. Lead 400 is preferably five separate leads bundled together. The center lead 401 may be advanced beyond the distal ends of the four outer leads 402 forming the outer surface of cube 405. In this embodiment, the inner lead may also be extended a variable distance from the distal tip of the outer tube. As an example, lead 400 of Figure 5 shows the situation when five (5) electrodes at its distal end are positioned in a planar configuration as shown in Figure 5A. This is accomplished by advancing inner lead 401 only as far as needed to position the most distal electrode in the same plane as those curled leads. As illustrated in Figures 6, 6A, 7 and 7A those skilled in the art will appreciate that any number of lead and electrode configurations may be possible and still be considered within the spirit and scope of the present invention. For example, another electrode may be on inner lead 401 and positioned right at the point where leads split apart. The lead of the present invention may also provide for drug delivery as shown in Figure 11 and discussed herein.

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Ten S. Wacker Drive, Ste. 3000
Chicago, Illinois 60606
Telephone: 312/715-1000
Fax: 312/715-1234

Each electrode may be individually connected to signal generator 14 through a conductor in cables 22 which is coupled to signal generator 14 in the manner shown in Figure 1. Alternatively, each electrode may be coupled to signal generator 14 in a manner disclosed in Application Serial No. 09/024,162 entitled "Living Tissue Stimulation and Recording Techniques with Local Control of Active Sites" and filed February 17, 1998. The electrodes of Figures 4-7 may be selectively powered as an anode, cathode or neither. The operator or patient preferably may also selectively adjust the energy, amplitude or pulse parameters delivered to each electrode. The selective control over each electrode may be achieved by signal generator 14 via programmer 20 or a separate controller such as that disclosed in Application Serial Nos. 09/024,162. Advantageously, the present invention allows the locus of excitation to be selectively adjusted and/or steered to precisely target portions of the brain to achieve the desired treatment therapy. The steering may be accomplished in the manner described in U.S. Patent No. 5,713,922 which is incorporated herein by reference in its entirety.

Figure 8 is an illustration of an alternative embodiment of a three dimensional electrode array having a lumen 800 for directing the trajectory of the electrical leads of the present invention. Lumen 800 is permanently introduced into the brain parenchyma to a region roughly in the center of the volume of brain the user wishes to influence. Lumen 800 has a proximal end 805 for accepting one or more leads 815A-818A and a distal end 810 having openings 815-818 for directing leads 815A-818A in accordance with a desired trajectory. Ends of leads 815A-818A may protrude from openings 815-818 as needed to achieve the desired geometric configuration. It is preferred that leads 815A-818A protrude out from openings 815-818 along a predetermined trajectory.

Advantageously, the present invention avoids any slicing movement of leads 815A-818A while moving outwardly from the central axis of lumen 800 thereby minimizing any risks of damage or bleeding to the brain tissue. Optionally, leads 815A-818A may be made of a silicon material having a predetermined bend or memory along its body to ensure that leads 815A-818A project from an opening at the desired angle.

Openings 815-818 preferably direct leads 815A-818A along a predetermined angle and trajectory. Figure 9 shows a cross-sectional view of cannula 905 along its distal end showing the two openings. Figure 9A illustrates a lead 920 as it is positioned within cannula 905 and lead end 910 is guided out from cannula 905 by opening 915. Figure 10 illustrates the interior portion 905 of a cannula capable of receiving four leads. Interior portion may be inserted within a standard cannula. Those skilled in the art will appreciate that any number of configurations are possible to achieve the desired geometric configurations of the electrodes. Additionally, lead members may contain more than one electrode near their distal end further expanding the geometric options for selectively activating subsections of brain volume.

The present invention is implanted by first implanting cannula 800 so that its distal end 810 is at a predetermined location within the brain. Each lead is then individually inserted within cannula 800 and positioned such that the electrode is at the desired location within the brain.

Figure 12 illustrates another embodiment of the present invention wherein four outer leads 450 are pre-formed so that the distal ends will curl out from the inner lead 465 when unconstrained by an introducing cannula 460. Outer leads 450 and inner lead 465 may be a single lead structure. Cannula 460 may be a standard cannula of a sufficiently large lumen to accept a plurality of leads.

Cannula 460 may also be utilized to implant the leads of Figures 4-7. Referring back to Figure 12, lead 450 may be given a predetermined curvature or memory so that the four outer leads 450 curl out when no longer constrained by the inner wall of cannula 460 as shown in Figure 12A. Again, the outer leads 450 preferably extend out into the brain parenchyma along a predetermined trajectory to minimize injury to brain tissue.

Optionally, the present invention may incorporate a closed-loop feedback system to provide automatic adjustment of the electrical stimulation therapy. The system may incorporate a sensor 130 to provide feedback to provide enhanced results. Sensor 130 can be used with a closed loop feedback system in order to automatically determine the level of electrical stimulation necessary to provide the desired treatment. Sensor 130 may be implanted into a portion of a patient's body suitable for detecting symptoms of the disorder being treated. Sensor 130 is adapted to sense an attribute of the symptom to be controlled or an important related symptom. Sensors suitable for this purpose may include, for example, those disclosed in U.S. Patent No. 5,711,316 entitled "Method Of Treating Movement Disorders By Brain Infusion" assigned to Medtronic, Inc., which is incorporated herein by reference in its entirety. In cases where the attribute of the symptom is the electrical activity of the brain, stimulating electrodes may be intermittently used to record electrical activity.

As shown in Figure 19, the output of sensor 130 is coupled by a cable 132 comprising conductors 134 and 135 to the input of analog to digital converter 206. Alternatively the output of the sensor 130 could communicate through a "body bus" communication system as described in U.S. Patent No. 5,113,859 (Funke), assigned to Medtronic which is incorporated by reference in its

entirety. Alternatively, the output of an external feedback sensor 130 would communicate with the implanted pulse generator 14 or pump 10A through a telemetry down-link. The output of the analog to digital converter 206 is connected to terminals EF2 BAR and EF3 BAR. Such a configuration may be one similar to that shown in U.S. Patent No. 4,692,147 ("'147 Patent") except that before converter 206 is connected to the terminals, the demodulator of the '147 patent (identified by 101) would be disconnected.

Alternatively, one or more electrodes implanted within the brain may serve as a sensor or a recording electrode. When necessary these sensing or recording electrodes may delivery stimulation therapy to the treatment site.

For some types of sensors, a microprocessor and analog to digital converter will not be necessary. The output from sensor 130 can be filtered by an appropriate electronic filter in order to provide a control signal for signal generator 14. An example of such a filter is found in U.S. Patent No. 5,259,387 "Muscle Artifact Filter, Issued to Victor de Pinto on November 9, 1993, incorporated herein by reference in its entirety.

Closed-loop electrical stimulation can be achieved by a modified form of the ITREL II signal generator which is described in Figure 13. The output of the analog to digital converter 206 is connected to a microprocessor 200 through a peripheral bus 202 including address, data and control lines. Microprocessor 200 processes the sensor data in different ways depending on the type of transducer in use. When the signal on sensor 130 exceeds a level programmed by the clinician and stored in a memory 204, increasing amounts of stimulation will be applied through an output driver 224.

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Ten S. Wacker Drive, Ste. 3000
Chicago, Illinois 60606
Telephone: 312/715-1000
Fax: 312/715-1234

The stimulus pulse frequency is controlled by programming a value to a programmable frequency generator 208 using bus 202. The programmable frequency generator provides an interrupt signal to microprocessor 200 through an interrupt line 210 when each stimulus pulse is to be generated. The frequency generator may be implemented by model CDP1878 sold by Harris Corporation. The amplitude for each stimulus pulse is programmed to a digital to analog converter 218 using bus 202. The analog output is conveyed through a conductor 220 to an output driver circuit 224 to control stimulus amplitude. Microprocessor 200 also programs a pulse width control module 214 using bus 202. The pulse width control provides an enabling pulse of duration equal to the pulse width via a conductor . Pulses with the selected characteristics are then delivered from signal generator 14 through cable 22 and lead 22A to the target locations of a brain B. Microprocessor 200 executes an algorithm to provide stimulation with closed loop feedback control as shown in U.S. Patent No. 5,792,186 entitled "Method and Apparatus of Treating Neurodegenerative Disorders by Electrical Brain Stimulation," and assigned to Medtronic, Inc., which is incorporated herein by reference in its entirety.

Microprocessor 200 executes an algorithm shown in Figures 14-18 in order to provide stimulation with closed loop feedback control. At the time the stimulation device 14 is implanted, the clinician programs certain key parameters into the memory of the implanted device via telemetry. These parameters may be updated subsequently as needed. Step 400 in Figure 14 indicates the process of first choosing whether the neural activity at the stimulation site is to be blocked or facilitated (step 400(1)) and whether the sensor location is one for which an increase in the neural activity at that location is equivalent to an increase in neural activity at the stimulation target or vice

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Ten S. Wacker Drive, Ste. 3000
Chicago, Illinois 60606
Telephone: 312/715-1000
Fax: 312/715-1234

versa (step 400(2)). Next the clinician must program the range of values for pulse width (step 400(3)), amplitude (step 400(4)) and frequency (step 400(5)) which device 14 may use to optimize the therapy. The clinician may also choose the order in which the parameter changes are made (step 400(6)). Alternatively, the clinician may elect to use default values.

The algorithm for selecting parameters is different depending on whether the clinician has chosen to block the neural activity at the stimulation target or facilitate the neural activity. Figure 14 details steps of the algorithm to make parameter changes.

The algorithm uses the clinician programmed indication of whether the neurons at the particular location of the stimulating electrode are to be facilitated or blocked in order to reduce the neural activity in the target nucleus to decide which path of the parameter selection algorithm to follow (step 420, Figure 15). If the neuronal activity is to be blocked, device 14 first reads the feedback sensor 130 in step 421. If the sensor values indicate the activity in the target neurons is too high (step 422), the algorithm in this embodiment first increases the frequency of stimulation in step 424 provided this increase does not exceed the preset maximum value set by the physician. Step 423 checks for this condition. If the frequency parameter is not at the maximum, the algorithm returns to step 421 through path 421A to monitor the feed back signal from sensor 130. If the frequency parameter is at the maximum, the algorithm next increases the pulse width in step 426 (Figure 16), again with the restriction that this parameter has not exceeded the maximum value as checked for in step 425 through path 423A. Not having reached maximum pulse width, the algorithm returns to step 421 to monitor the feedback signal from sensor 130. Should the maximum pulse width have been reached, the algorithm next increases amplitude in a like manner as shown in steps 427 and

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Chicago, Illinois 60606
Telephone: 312/715-1000
Fax: 312/715-1234

428. In the event that all parameters reach the maximum, a notification message is set in step 429 to be sent by telemetry to the clinician indicating that device 14 is unable to reduce neural activity to the desired level.

If, on the other hand, the stimulation electrode is placed in a location which the clinician would like to activate in order to increase an inhibition of the target nucleus, the algorithm would follow a different sequence of events. In the preferred embodiment, the frequency parameter would be fixed at a value chosen by the clinician to facilitate neuronal activity in step 430 (Figure 17) through path 420A. In steps 431 and 432 the algorithm uses the values of the feedback sensor to determine if neuronal activity is being adequately controlled. In this case, inadequate control indicates that the neuronal activity of the stimulation target is too low. Neuronal activity is increased by first increasing stimulation amplitude (step 434) provided it doesn't exceed the programmed maximum value checked for in step 433. When maximum amplitude is reached, the algorithm increases pulse width to its maximum value in steps 435 and 436 (Figure 18). A lack of adequate reduction of neuronal activity in the target nucleus, even though maximum parameters are used, is indicated to the clinician in step 437. After steps 434, 436 and 437, the algorithm returns to step 431 through path 431A, and the feedback sensor again is read.

It is desirable to reduce parameter values to the minimum level needed to establish the appropriate level of neuronal activity in the target nucleus. Superimposed on the algorithm just described is an additional algorithm to readjust all the parameter levels downward as far as possible. In Figure 14, steps 410 through 415 constitute the method to do this. When parameters are changed, a timer is reset in step 415. If there is no need to change any stimulus parameters before the timer

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Ten S. Wacker Drive, Ste. 3000
Chicago, Illinois 60606
Telephone: 312/715-1000
Fax: 312/715-1234

has counted out, then it may be possible due to changes in neuronal activity to reduce the parameter values and still maintain appropriate levels of neuronal activity in the target neurons. At the end of the programmed time interval, device 14 tries reducing a parameter in step 413 to determine if control is maintained. If it is, the various parameter values will be ratcheted down until such time as the sensor values again indicate a need to increase them. While the algorithms in Figure 14 follow the order of parameter selection indicated, other sequences may be programmed by the clinician.

The features and advantages of the present invention for steering an electric field within a brain, a spinal cord, or a peripheral nerve may be implemented in numerous applications. It is generally desirable to excite particular neural tissue elements of the brain to provide a certain treatment such as treatment of a neurological disorder, the relief of chronic pain or to control movements. Often, nearby groups of neurons or axons, e.g., the optic nerve, internal capsule, or medial lemniscus, are in special orientations and groupings. It may be advantageous to avoid affecting them (e.g., preventing stimulation of the perception of the flashes of light) or deliberately to affect them (e.g., excite or inhibit axons of passage). Advantageously, the present invention allows steering of the electrical filed in two- or three-dimensional space such that the precise location and orientation of the electrodes is less critical.

Closed-loop feedback control may also be implemented to steer the electric field to more precisely affect the desired treatment vollume of neural tissue.

Referring back to Figure 11, the present invention may also be implemented within a drug delivery system. In this embodiment, the therapy delivery device is a pump 10A and the therapy delivery element is a catheter 23. A therapy delivery device or pump 10A made in accordance with

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Ten S. Wacker Drive, Ste. 3000
Chicago, Illinois 60606
Telephone: 312/715-1000
Fax: 312/715-1234

the preferred embodiment may be implanted below the skin of a patient. The device has a port 27 into which a hypodermic needle can be inserted through the skin to inject a quantity of a liquid agent, such as a medication or drug. The liquid agent is delivered from pump 10A through a catheter port 20A into a therapy delivery element or a catheter 23. Catheter 23 is positioned to deliver the agent to specific infusion sites in a brain (B). Pump 10A may take the form of the device numbered 10 that is shown in U.S. Patent No. 4,692,147 (Duggan), assigned to Medtronic, Inc., Minneapolis, Minnesota, which is incorporated by reference in its entirety.

The distal end of catheter 23 terminates in a cylindrical hollow tube 23A having a distal end 115 implanted into a portion of the brain B by conventional stereotactic surgical techniques. Tube 23A is surgically implanted through a hole in the skull 123. Catheter 23 is joined to pump 10A in the manner shown.

The present invention may be used to deliver treatment therapy to any number of sites in the brain. Particular sites within the brain include, for example, the subthalamic nucleus (STN), the peduncular pontine nucleus (PPN), the caudate or putamen, the internal and external pallidum, the cingulum, the anterior limb of the internal capsule, the anterior nucleus (AN), the centremedian (CM), the dorsal medial nucleus and other nuclei of the thalamus, the hippocampus and other structures in the temporal lobe, the hypothalamus and other structures of the diencephalon, the pons, the medulla, the corext, the cerebellum, the lateral geniculate body, and the medial geniculate body. The desired configuration of the electrodes would depend upon the structure of the portion of the brain to be stimulated or infused and the angle of introduction of the deep brain cannula.

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Telephone: 312/715-1000
Fax: 312/715-1234

Further, lamina for visual fields are found in the lateral geniculate body, and lamina for tones for hearing are found in the medial geniculate body. Hence, steering of excitation or inhibition by use of this invention can be most useful.

Leads of the present invention may also be placed into the parenchyma of the spinal cord. For example, an electrode array may be located in the region of a specified spinal cord segment where neural tissue related to the bladder may be influenced. Selective activation of regions of the ventral horn of the spinal cord in these spinal segments may enable selective activation of specific actions related to bladder function. Alternatively, placement of leads in the region of the connus medullaris (Figure 22) or cauda equina (Figure 21) may further enhance the ability to selectively activate element of urinary bladder control. Leads 975 or 980 of Figures 21 or 22 may be implanted under known techniques for implanting leads within the spinal cord.

As shown in Figure 23, leads of the present invention may also be placed in a peripheral nerve to provide selective activation of individual nerve fascicles or neurons each innervating a different body region or subserving a different physiological function. Selective activation individual nerve fascicles or neurons may allow discrimination of regions of body surface when evoking paresthesia activation to treat chronic pain. Alternatively, such an embodiment would allow selective activation of different muscle groups when performing functional electrical stimulation.

Advantageously, the present invention may be used to selectively steer and control the stimulation of neurons or neural tissue to deliver a desired treatment therapy. Those skilled in that art will recognize that the preferred embodiments may be altered or amended without departing from the true spirit and scope of the invention, as defined in the accompanying claims. For example, the

present invention may also be implemented within a drug delivery system where the leads are implanted within the brain in accordance with the present invention to provide electrical stimulation as well as delivery of one or more drugs.